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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,796	12/21/2001	Masamichi Toba	Q-67818	6985

7590 07/29/2003

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EXAMINER
MARX, IRENE

ART UNIT	PAPER NUMBER
1651	5

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,796	TOBA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The application should be reviewed for errors.

The status of the parent case(s) should be updated .

The amendment filed 12/21/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the proposed changes at page 3, lines 19-25 wherein "living body" is defined; page 4 lines 1-19, wherein "manganese-containing natural material" is defined; page 8, lines 9-22, in the phrase " additional effects ... by taking advantage of the presence of an activity of these anti-oxidant component".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 8 are vague, indefinite and confusing in the recitation of "in the presence of a tea extract or a powdered tea", since it is doubted that the mere "presence" of a very diluted drop or two of tea is sufficient to achieve any results different from providing any fermented milk of skim milk fermented with *L. plantarum*.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwabara (GB 1,197,257) taken with Hammes *et al.*, ATCC Catalogue of Bacteria and Hara, U.S. Patent No. 4,673,530.

The claims are drawn to a method of producing in vivo antioxidation in a living subject by feeding a fermented milk product produced by *Lactobacillus plantarum* having Mn-catalase activity in the presence of tea to a living subject.

The cited reference discloses a fermented milk product produced by a *Lactobacillus* strain in the presence of tea extract which appears to be identical to the presently claimed product (see, e.g., Example 1) since the strain taught therein, *L. acidophilus (L. delbrueckii)*, would reasonably be expected by one of ordinary skill in the art to possess catalase activity. The ATCC Catalogue of Bacteria, page 169 adequately demonstrates that strains of *L. acidophilus* have been reclassified as *L. delbrueckii.* Hammes *et al.* indicate that *L. delbrueckii* are catalase positive (See, e.g., page 1562, col. 2) and possess the ability to dismutate superoxide in the presence of manganese. It is noted that the fermentation with the *Lactobacillus* strain continues after the tea extract and sugar are added to the fermented milk product. Therefore, the fermented product disclosed by the reference and the instant fermented milk are presumed to be substantially similar. The product is clearly intended for ingestion by a living subject, since the flavor, taste, consistency and nutrition thereof is touted (See, e.g., page 2, col. 2, lines 84-93). The production of catalase by *L. plantarum* ATCC 14431 is an intrinsic property thereof, as adequately demonstrated by the ATCC Catalogue, page 175.

Moreover, even if the claimed fermented milk product produced by a *Lactobacillus* strain in the presence of tea extract is not identical to the referenced product with regard to some unidentified properties, the differences in effect between feeding this product and feeding the claimed product to a living subject cannot be readily ascertained. It is deemed that the products are so similar as to produce the identical effects with respect to antioxidant effects, particularly in the absence of evidence to the contrary.

It is noted that the correlation between the fermented milk and the production of superoxide dismutase activity and catalase activity is not clear in the context of the instant

invention. For example, there is no clear identification of the target for the *in vivo* antioxidation or of the dosage of the fermented milk to be ingested. This amount would reasonably be expected to depend at least on the nature, size and age of the individual to be treated. Similarly, it is unclear whether the product is intended to induce, stimulate or provide the targetted individual with superoxide dismutase activity and catalase activity or to what extent. In this regard, there is no clear indication in the claimed invention whether or not the "fermented milk" provides live microorganisms or active enzymes. Merely ingestion of traces of a fermented milk is unlikely to have a significant antioxidation effect.

Moreover, the antioxidant effects of tea were well known at the time the claimed invention was made, as adequately demonstrated by Hara. It is noted that green tea is the same type of tea as is used in the instant specification, which naturally contains manganese. See, e.g., Examples.

Furthermore, the composition fed to a living subject is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons of methods of ingesting same, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the teachings of Kuwabara (GB 1,197,257) by providing the composition to a living subject for its delicious flavor, better taste and better consistency and for the expected benefit of providing antioxidation effects *in vivo,* as suggested by the teachings of Hara.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone

number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Primary Examiner
Art Unit 1651